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July 11, 2005

Via Federal Express

Hon. Tonianne J. Bongiovanni, United States Magistrate Judge
United States District Court
Clarkson S. Fisher Federal Building and U.S. Courthouse
402 East State Street
Trenton, N.J. 08608

Re: Garber, et al. v. Pharmacia Corporation, et al.
Civ. No. 03-1519 (AET) (Consolidated)

Dear Judge Bongiovanni:

This firm represents The New York Times Company, publisher of *The New York Times* ("*The Times*"). Please accept this letter-brief in lieu of a more formal submission pursuant to this Court's Order permitting *The Times* to file an Amicus brief on behalf of plaintiff's application to modify the Stipulation and Protective Order dated July 26, 2004 ("the Order") in this matter.

THE INTEREST OF THE AMICUS

The New York Times Company is the publisher of *The New York Times*. The newspaper's weekday circulation is the highest in the nation among metropolitan dailies at more than

1.1 million daily and 1.7 million on Sunday. It actively covers issues concerning the public health and welfare as well as the pharmaceutical industry and maintains bureaus in both Newark and Trenton.

The Times has devoted significant time and resources to the coverage of the issues involving the safety and efficacy of prescription drugs, COX-2 inhibitors in general and Celebrex in particular. There can be no doubt that the safety and efficacy of prescription drugs is a major issue facing both the American public and its elected representatives. The more information available to the public on these issues, the more individuals can make competent decisions concerning use of these drugs and the more the public can understand and encourage their representatives to take appropriate action, whatever that may be.

ARGUMENT

I. THE SUBJECT MATTER OF THE DOCUMENTS AT ISSUE INVOLVE IMPORTANT PUBLIC SAFETY ISSUES

In late 2004, Merck & Company withdrew Vioxx, a popular anti-inflammatory drug, from the market because of information showing it may increase the risk of heart attacks and stroke. More recent revelations show similar problems with other COX-2 inhibitors that have been marketed directly to consumers, such as Pfizer's Celebrex and Bextra, deepening an important national debate on the efficacy of the pharmaceutical approval process, the safety monitoring process, and the degree to which pharmaceutical companies are not candid about risks associated with these drugs. The debate has been further driven by Pfizer's recent admission that it never revealed to the FDA a 1999 study showing that the number of Celebrex patients suffering heart attacks was almost four times that of those taking a placebo. Celebrex is one of the world's most widely prescribed medicines, with sales of \$3.3 billion in 2004. The Food and Drug Administration's web site has included a warning

stating that: “Based on emerging information, including preliminary reports from one of several long term National Institutes of Health (NIH) prevention studies, the risk of cardiovascular events (composite endpoint including MI, CVA and death) may be increased in patients receiving Celebrex. FDA will be analyzing all available information from these studies to determine whether additional regulatory action is needed.”

The public clearly has an interest in understanding, as fully and as soon as possible, the public safety issues involved in these drugs’ approvals and the decision-making process within the FDA and Pfizer concerning licensing of Celebrex. In light of the acknowledged “lapses” by the FDA in its drug oversight and the apparent withholding of certain studies by Pfizer, it is even more difficult for the public to expect that they can rely on the materials presented by the government and the industry.

The Times believes that it is important to provide the public with greater access to discovery materials that Pharmacia has apparently taken upon itself to designate as confidential under the Order. So far as *The Times* understands it, there are no substantial privacy interests or business secrets at issue here and no compelling reasons to keep these materials under a protective order. Specifically, *The Times* believes that the Court should modify the Confidentiality Order so that it does not prohibit public access to the documents thus far designated as confidential by Pharmacia.

Under the law, there is a presumption of access to discovery materials, and a court may deny public access to discovery documents only upon a proper showing of good cause. *The Times* believes that there is no good cause to maintain a confidentiality designation on the documents in question.

**II. THE PROTECTIVE ORDER SHOULD BE MODIFIED SO
AS TO ALLOW GREATER PUBLIC ACCESS TO THE
DISCOVERY MATERIALS IN THIS CASE**

A. Courts May Modify Confidentiality Orders to Accommodate Important Public Interests

This Court has ruled that *The Times'* interests would be adequately represented by plaintiffs in seeking to modify the protective order. *The Times* respectfully disagrees, but is not appealing that ruling and is instead filing the within amicus brief. Yet defendants' underlying argument, if adopted, would make it impossible for plaintiffs' to represent *The Times'* interests: Defendants argue that since plaintiffs agreed to the protective order, the fact that there is a strong public interest in favor of modifying that Order to allow greater public access is irrelevant¹. In other words, plaintiffs are precluded from arguing that a "public interest" exception exists to modify the protective order and they should be bound to follow it. Defendants are incorrect in their recital of the law.

The Times believes that the Plaintiff's February 15 application is in accord with the facts and the law and that this Court should modify the Confidentiality Orders so that they do not prohibit public access to the documents designated to this point as confidential by Pharmacia.

"It is well established that the fruits of pre-trial discovery are, in the absence of a court order to the contrary, presumptively public." *San Jose Mercury News, Inc. v. United States Dist. Ct.*, 187 F.3d 1096, 1103 (9th Cir. 1999). In addition, absent a protective order, "parties to a law suit may disseminate materials obtained during discovery as they see fit." *Jepson, Inc. v. Makita Elec. Works, Ltd.*, 30 F.3d 853, 858 (7th Cir. 1994); *Phillips v. GMC*, 307 F.3d 1206, 1210 (9th Cir. 2002).

As noted in the February 15 Motion, if these materials are not within the ambit of a confidentiality order, a party may make them available to the public.

Moreover, as set forth by Plaintiffs, the types of sweeping confidentiality designations made by plaintiff are disfavored. *Pansy* stands for the “impropriety of the issuance of broad confidentiality orders, which signaled a shift from the previous practice of judicial endorsement of such stipulations.” *Glenmede Trust Co v. Thompson*, 56 F.3d 476, 481, n.8 (3d Cir. 1995).

As the Third Circuit held in *Pansy*, “[i]t is well-established that a district court retains the power to modify or lift confidentiality orders that it has entered,” and “[t]he issue of whether an order of confidentiality should be modified is separable from the question concerning whether a [document] subject to that order is a judicial record for purpose of the right of access doctrine.” 23 F.3d at 784-85. *Leucadia, Inc. v. Applied Extrusion Technologies, Inc.*, 998 F.2d 157 (3rd Cir. 1993); *Republic of Philippines v. Westinghouse Elec. Corp.*, 139 F.R.D. 50 (D.N.J.), *stay denied*, 949 F.2d 653 (3rd Cir. 1991).

A party seeking to impose or maintain confidentiality restrictions over documents exchanged in discovery or created in other stages of the litigation has the burden of demonstrating “good cause” for the protective relief, by “specifically demonstrat[ing] that disclosure will cause a clearly defined and serious injury.” *Glenmede Trust Co*, 56 F.3d 476 at 483. “Broad allegation of harm, unsubstantiated by specific examples, . . . will not suffice.” *Id.* See also, *Pansy*, 23 F.3d at 786. Conclusory or stereotypical assertions are insufficient. *Exum v. United States Olympic Committee*, 209 F.R.D. 201, 206 (D. Colo. 2002). Nor can one party allege surprise that that the potential for a motion

¹ In addition, defendants’ argue that in seeking to modify the protective order, rather than working through it, plaintiffs have essentially violated and subverted that Order. See Defendants’ April 1, 2005 Letter to the Court at 6-9.

for intervention exists. “Where public entities and issues of great public concern are involved, parties should be aware of potential disclosure if *good cause* can no longer be demonstrated.” *D.M. v. Terhune*, Civil Action No. 96-1840 (August 18, 2000)(Hughes, U.S.M.J.).

Rule 26(c)’s good cause requirement means that “[a]s a general proposition, pretrial discovery must take place in the public unless compelling reasons exist for denying the public access to the proceedings.” *American Telephone & Telegraph Co. v. Grady*, 594 F.2d 594, 596 (7th Cir. 1978) *cert. denied* 440 U.S. 594 (1979). The presumption of access is strong.

Any other conclusion effectively would negate the good cause requirement of Rule 26(c). Unless the public has a presumptive right of access to discovery materials, the party seeking to protect the materials would have no need for a judicial order since the public would not be allowed to examine the materials in any event. *In re Agent Orange Liability Litigation*, 821 F.2d 139, 145-46 (2d Cir.) *cert. denied* 484 U.S. 926 (1987), *aff’d* 104 F.R.D. 559, 567 (E.D.N.Y. 1985).

Plaintiffs have followed the correct procedure: A party seeking to modify a confidentiality order “must come forward with a reason to modify the order.” *Pansy*, 23 F.3d at 790. Once the Court is satisfied that a reason exists to modify the order, the District Court must “use the same balancing test that is used in determining whether to grant such orders in the first instance,” with one difference: one of the factors the court should consider in determining whether to modify the order is the reliance by the original parties on the confidentiality order.” *Id.* The *Pansy* Court added, however, that the original parties’ reliance was not outcome determinative, but simply one factor to consider.

Defendants also protest that they cannot be expected to itemize “good cause” for more than 400,000 documents; in making this argument they are creating a straw man. Of course it is correct that in complex litigation with tens of thousands of documents, umbrella orders serve a useful purpose and no party can be expected to justify the confidentiality of each individual document. However, the party seeking to enforce confidentiality should be required, however, to justify continued restrictions on each category of class of documents sought to be withheld. *See, e.g., Charlie H. v. Whitman*, 213 F.R.D. 240 (D.N.J. 2003)435-436.

B. The Order Sweeps Too Broadly and Should be Modified

The Times submits that these factors militate in favor of modifying the restrictions on disclosure of the discovery at issue. As the Seventh Circuit observed: “[I]n our present society many important social issues become entangled to some degree in civil litigation. Indeed, certain civil suits may be instigated for the very purpose of gaining information for the public. Often actions are brought on behalf of the public interest on a private attorney general theory. Civil litigation in general often exposes the need for governmental action or correction. Such revelations should not be kept from the public.” *Chicago Council of Lawyers v. Bauer*, 522 F.2d 242, 258 (7th Cir. 1975), *cert. denied*, 427 U.S. 912 (1976).

The Third Circuit has identified the following factors to be weighed in the district court’s balancing process:

- (1) whether disclosure will violate any privacy interests;
- (2) whether the information is being sought for a legitimate purpose or for an improper purpose;
- (3) whether disclosure of the information will cause a party embarrassment;
- (4) whether confidentiality is being sought over information important to public health or safety;

- (5) whether the sharing among litigants will promote fairness and efficiency;
- (6) whether the party benefiting from the order of confidentiality is a public entity or official; and
- (7) whether the case involves issues important to the public.

Glenmede, 56 F.3d at 483 (citing and summarizing *Pansy*, 23 F.3d at 787-91).

The Times believes that based upon the representations of plaintiffs' counsel, there are no privacy interests or proprietary interests at stake and there can be no serious argument that plaintiffs seek these materials for an improper purpose. In fact, factors four and seven are right on point: the material sought to be accessed involves the health and safety of the general public and important public issues concerning government regulation of the pharmaceutical industry.

The most likely underlying reason for defendants' opposition is some sort of vague fears that they will be embarrassed in the media. However, general allegations of injury to reputation and client relationships or embarrassment that may result from dissemination of privileged documents is insufficient to justify judicial endorsement of an umbrella confidentiality agreement. *Glenmede Trust Co.*, 56 F.3d at 484. "We have typically viewed the "embarrassment" factor in terms of non-pecuniary harm to individuals; however, the primary measure of the well-being of a business is pecuniary."

It is very nature of the health and safety issues involved – combined with the need of the public to monitor corporate responsibility, which militates for disclosure. "If a [confidentiality order] involves issues or parties of a public nature, and involves matters of legitimate public concern, that should be a factor weighing against entering or maintaining an order of confidentiality." *Pansy*, 23 F.3d at 788. In *Charlie H. v. Whitman*, *supra.*, this Court weighed the same factors in deciding

whether a confidentiality order entered by the Court in a class action brought against the State of New Jersey should prohibit public access to records of the Division of Youth and Family Service in light of reports of neglect and deaths of wards in its care. In that case, there were significant privacy issues, which were surmounted through a redaction process, and arguments by the State that dissemination of the materials violated State law, which were rejected by the Court because of the overriding public interest. The Court similarly rejected arguments that the State had relied on the existing protective order, noting that “public entities should be sensitive to the reality that events often change circumstances.” *Id.* at 251. The court addressed various categories of documents that were deemed confidential in a protective order and went through them category by category.

Although Pharmacia is not a public entity, public knowledge of the issues involved in this matter may actually have a much wider impact on a national – and international -- public than those involving DYFS. Judge Hughes concluded that public interest in the DYFS matter was “of great public interest, impacting on the health and safety concerns of the children not only under the care of DYFS but others who may one day come into contact with DYFS.” *Id.* at 248. The same could be said for this matter, where the information impacts on the health and safety concerns for those who use or may use Celebrex or other COX-2 inhibitors or who are concerned with FDA supervision of the drug approval process.

Indeed, public disclosure in this action advances important social goals. Openness here, as in other judicial proceedings, allows the people to monitor the court system, to ascertain for themselves that justice is being done, and to know that judicial resources are being used prudently. *U.S. v. Criden*, 648 F.2d 814, 819 (3d Cir. 1981) (describing common law right of access). *In re*

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Reporters Committee for the Freedom of the Press, 773 F.2d 1335, 1351 (D.C. Cir 1981) (describing the right of access to trial exhibits in a civil case). It also allows the public to have a more detailed view of the federal regulatory process, including the decisionmaking and approval process for new medications. This matter and these materials involve important public policy issues that deserve public access.

CONCLUSION

For the foregoing reasons, this Court should modify the Confidentiality Order in accordance with Plaintiff's February 15 Motion, and grant such other and further relief as the Court deems just and proper.

Respectfully Submitted,

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Cc: Attached Service List